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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,042	11/16/2001	Hiroyuki Miyata	0283-0161P	7946

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EXAMINER

ANDERSON, REBECCA L

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/988,042

Applicant(s)

MIYATA ET AL.

Examiner

Rebecca L Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 6.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1-14 are currently pending in the instant application. Claims 1-13 are rejected. Claim 14 has utility and also appears allowable over the prior art of record.

Response to Amendment

The declaration under 37 CFR 1.132 filed 30 October 2002 is insufficient to overcome the rejection of claims 1-6 based upon 35 U.S.C. 101 and 112 1st paragraph as set forth in the last Office action because: Applicant has not shown by evidence how all the species encompassed by the compound of formula (I) as found in claim 1 have utility. Applicant has only provided utility for a single species, specifically the species as found in claim 14. As evidence of utility for the species of claim 14, applicant has provided example 1 in the declaration which discloses how to prepare 5 methylproline methyl ester from the compound as found in claim 14, however, this cannot be concluded to provide evidence for all compounds of the formula I. Applicant has also provided an additional example and reference example for the preparation of 5-(n-propyl)-proline methyl ester from the species of formula (I), specifically, 3-(R)-1-phenylethyl-7a-methoxy-6-propyl-4H-pyranol [3,2-d]-oxazol-2(3H)-one in the declaration, however, applicant has not provided evidence that the 5-(n-propyl)-proline methyl ester has any utility, and therefore, has not provided an example of utility for 3-(R)-1-phenylethyl-7a-methoxy-6-propyl-4H-pyranol [3,2-d]-oxazol-2(3H)-one. Therefore, the declaration provided is insufficient to overcome the rejections of claims 1-6.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4, 5-6 and newly added claims 7-13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

For essentially the same reasons as those set forth in Paper No. 2, claims 1-13 lack a specific or substantial asserted utility or a well established utility because the specification provides the utility for the claimed compound of formula (I), as found in claim 1, as a "starting material or an intermediate for synthesizing a pharmaceutical product or an agricultural chemical and as a starting material for synthesizing other fine chemical products (page 1, lines 10-15). This utility is not a substantial utility that defines a "real world" use. According to the MPEP section 2107.07 "substantial utility" is defined as a utility that does not require further research to identify or confirm the "real world" context of use. An example, according to section 2107.07 of the MPEP, of a utility that requires carrying out further research to identify or confirm the context of use is "a claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility." There are many pharmaceutical products that are useful for treating many different diseases, however, there is no known pharmaceutical product that is useful in treating all diseases. Without specific examples of pharmaceutical products and direction towards treatment of types of diseases, it would require someone of ordinary skill in the art further research to identify the use of

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the claimed compound. In the instant case, the only example compounds produced by applicants claimed compounds is 5-methylproline methyl ester (from page 41 of the specification and page 3 of the declaration) and 5-(n-propyl)-proline methyl ester (page 5 of the declaration). The 5-methylproline methyl ester has a specific utility as found in EP 0 618 926, while the 5-(n-propyl)-proline methyl ester has no stated specific or substantial utility. The showing of utility for the intermediate 5-methylproline methyl ester only provides utility for the specific compound of claim 14. The production of 5-(n-propyl)-proline methyl ester does not provide support for a specific and substantial utility since no utility is given for this intermediate and the pharmaceutical products and agricultural compounds are still not given in examples and a direction for use of the final products is not given. Besides the example of 5-methylproline methyl ester as one of the products of the claimed compound in a reaction, the applicant fails to provide direction so that one of ordinary skill in the art would know how to use any other claimed compounds but that of claim 14. Again, EP 0618926 and the declaration under 35 U.S.C. 1.132, which has established utility for the specific compound of claim 14, has not established utility for all the compounds of formula I as instantly claimed, i.e. these other compounds of formula I have not been shown to be useful for the preparation of the known intermediate, 5 methylproline methyl ester. The declaration under 35 U.S.C. 1.132 fails to show how any other claimed compounds of the formula I can be used to make the known intermediate of 5 methylproline methyl ester. The second example of the declaration shows how to make 5-(n-propyl)-proline methyl ester, which is not shown to have a substantial utility and is not found as a starting material in EP 0618926.

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In regards to the production of agricultural chemicals as the use for the claimed compound, agricultural chemicals can be used in various ways such as pesticides, fungicides, and herbicides. Without specific examples of agricultural chemicals or a direction towards the general use of these agricultural chemicals, it would require someone of ordinary skill in the art further research to identify the use of the claimed compound. Finally, the use of the claimed compound as starting material or an intermediate to make fine chemical products without specific examples of these fine products or their intended use requires someone of ordinary skill in the art to perform further research to identify the use of the claimed compound. Therefore, claims 1-4 and 7-13 are rejected because the specification fails to provide a specific and substantial utility for the compounds as claimed.

In view of the lack of utility rejection of claims 1-4 and 7-13, claims 5-6 are also rejected. According to MPEP 2107.07, another example of a utility that requires further research to identify or confirm the context of use is "a method of making a material that itself has no specific, substantial, and credible utility. Since the claimed compound has no substantial and specific utility, the process of making the compound as claimed in claims 5-6 is also rejected under lack of utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Allowable Subject Matter

Claim 14 appears allowable over the prior art of record.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703) 605-1157. Mrs. Anderson can normally be reached Monday through Friday 7:00AM to 3:30PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.



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